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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,940	09/27/1999	JENNIFER L. HILLMAN	PF-0346-1-DI	1067

27904 7590 09/09/2002

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EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/405,940	Applicant(s) Hillman et al.
	Examiner G.R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10/15/01 and 7/01/02

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1, 2, 13, and 24-26 is/are pending in the application.

4a) Of the above, claim(s) 24-26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, and 13 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

DETAILED ACTION

1. The request filed on 7/01/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/405,940 is acceptable and a CPA has been established. An action on the CPA follows. The declaration of Lars Michael Furness under 37 CFR 1.132, filed 10/15/01, has been entered.

2. Claims 1, 2, and 13 are being acted upon.

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1, 2, and 13 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, for the reasons set forth in Papers No. 7 and 10, mailed 10/24/00 and 4/04/01, respectively.

Applicant has submitted a declaration under 37 CFR 1.132 by Lars Michael Furness in support of the invention of the instant claims. When considering the probative value of a 1.132 declaration the Examiner must consider several factors. Included in those factors are the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion (MPEP 716.01(c)). Note the phrases "interest of the expert" and "expert's opinion." It would seem that the declarant must first be established as an expert in the field for the opinion to be of any probative. "Expert" can be defined as "One with special skill or knowledge representing mastery of a particular subject," (Webster's Ninth New Collegiate Dictionary, 1990). In the instant declaration, the declarant offers his opinion on what one of skill in the art would have known at the time of the invention. It is clear then that an expert must be established as significantly more skilled even than one of skill in the art. In the biological sciences, where one of skill in the art often has at least doctoral level training, one with mastery of the subject would necessarily have at least that level of training, and additionally, some demonstration of said mastery such as a body of peer-reviewed publications, i.e., a significant *curriculum vitae*. In the instant case, the declarant has

provided a brief *resume* indicating just a bachelor's level of education and no peer-reviewed publications. Thus, it is unclear how the declarant can be considered an expert in the field encompassed by the instant claims. Assuming, *arguendo*, that Mr. Furness can be considered an expert, and thus capable of rendering an expert opinion, Mr. Furness's interest in the outcome of the case must also be taken into account. Clearly, as an employee of the assignee, Mr. Furness's opinion (expert or otherwise) cannot be considered impartial. Finally, it must be noted that the declaration, while comprising ten additional reference, and approximately the same number of pages of argument, provides no additional factual support for the assertion that the EST of the instant claims is expressed as a T cell receptor beta chain protein.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence fails to establish a specific and substantial asserted utility or a well-established utility for the invention of the instant claims.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, and 13 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, for the reasons set forth in Papers No. 7 and 10, mailed 10/24/00 and 4/04/01, respectively.

Applicant's arguments, filed 10/15/01, have been fully considered but have not been found convincing, see paragraph 4 above.

7. Claim 2 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons set forth in Papers No. 7 and 10, mailed 10/24/00

and 4/04/01, respectively.

Applicant's arguments, filed 1/29/01, have been fully considered but have not been found convincing. Applicant argues that the new claim language limiting the claimed protein to 90% sequence identity and IL-2 inducing activity is sufficient to overcome the previous rejection. However, said claim still encompasses a virtually unlimited number of proteins while the specification still provides an insufficient written description of said proteins.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 5, 2001

Pat J. Nolan
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